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Ark Therapeutics Group plc

Positive Results of Trinam® Gene Therapy Presented at American College of Surgeons Congress

- Breakthrough treatment for kidney failure patients -

- Access grafts remain functional three times longer than previous procedures-

Ark Therapeutics Group plc ("Ark") today announces the publication of positive results from an ongoing Phase II trial of Trinam®, its novel gene therapy to prevent blood vessels blocking in kidney dialysis patients who have undergone vascular access graft surgery. The data to date, which will be presented later today at the 2005 Annual Clinical Congress of the American College of Surgeons in San Francisco, show that access grafts continue to remain functional three times longer than previous procedures, with no systemic distribution of the inserted gene being found.

Patients in renal failure depend on good vascular access for haemodialysis, which removes blood from the body, cleans it and returns it, three times a week. Without dialysis these patients would die. A common method of gaining access to the circulatory system is via an artificial blood vessel (vascular access graft) sewn between an artery and a vein in the forearm. However, in a majority of patients, the grafts become blocked due to overgrowth of muscle tissue inside the blood vessel (intimal hyperplasia) and this requires further complex surgery to allow dialysis to take place.

Trinam® is a combination of a vascular endothelial growth factor gene in an adenoviral vector (Ad-VEGF-D) and Ark's biodegradable local delivery collagen collar device (EG001). At the end of the access graft surgery procedure, the collar is fitted around the outside of the vein/graft join. The VEGF gene solution, which reduces the likelihood of blood clots and intimal hyperplasia, is then injected into the space between the wall of the collar and the blood vessel. This unique method of administration of the gene localises its delivery to the target tissue site, maximising efficacy, avoiding systemic distribution and thus minimising the potential for side effects.

The Phase II trial of Trinam® is an ongoing, open-label,s tandard care-controlled clinical trial that primarily assesses safety, with efficacy as a secondary measure. In the study, six patients with end-stage renal disease dependent on regular haemodialysis for kidney function received one dose of 4×10^9 particles at the time they underwent surgery either to implant a first vascular access graft or to insert a new graft in a different location after failure of a previous access procedure.

After as long as a year of follow-up, none of the patients exhibited serious side effects, other than those consistent with the nature of the operation and condition and no systemic distribution of Trinam® was evident. The VEGF gene was not detected outside the specific vein area treated by the surgeon. Whilst one patient had to be withdrawn from the trial because of an infection believed to have been contracted at the time of surgery, the remaining five patients had encouraging prolonged graft patency. Four patients ongoing in the trial had previously had multiple failed access procedures prior to the trial. The mean patency of previous access procedures in these patients was 4.5 months. Using Trinam®, the mean patency has been extended so far to 14 months and in all of these patients the grafts continue to remain patent and functional for dialysis.

The study remains ongoing with a higher dose of VEGF (4×10^{10}) particles and is being conducted at Duke University, The University of Miami and Vascular and Transplant Specialists in Norfolk, Virginia.

In the US and Europe, there are an estimated 150,000 cases each year where Trinam® might be used. In patients fitted with haemodialysis access grafts, up to 60% of the grafts block within a year of being inserted and repeat surgery shows more rapid failure rates[1]. There are currently no approved drug therapies to reduce failure rates of haemodialysis access graft procedures. The clinical need for an effective treatment is such that the National Institutes of Health in the US has highlighted it as a priority requiring a solution in the Healthy People Directive 2010.

Commenting on the results, Dr Jeffrey Lawson, Associate Professor of Surgery and Pathology at Duke University, North Carolina and lead investigator in the trial, said:

"Instead of having the majority of vascular access grafts re-operated on within a year, sometimes each two or three times, this treatment preserves the graft's functionality for a longer period, so patients can go about their lives normally and have fewer surgical interventions and complications. By delaying the rate of failure of dialysis access grafts, the treatment may also save healthcare systems some $15,000 to $20,000 for each intervention. This kind of technology is very exciting and some day will be in general use."

Nigel Parker, Chief Executive of Ark, added:

"These are extremely encouraging results, representing a breakthrough in targeted gene medicine and demonstrating Ark's expertise and leadership in this emerging field. We had planned to establish primarily safety and systemic distribution in this low dose group and to get human proof-of-principle results of this magnitude exceeds our expectation. We are particularly pleased to see that patients' grafts continue to remain open after a period far beyond what might be expected. If validated during the remainder of the development programme, Trinam® has the potential to save many lives, to bring substantial improvement to the quality of life of chronic renal failure patients undergoing haemodialysis, and to save significant healthcare costs."

[1]*Reference: Rosas SE et al, Determinants of successful synthetic haemodialysis vascular access graft placement. J. Vasc. Surg. 2003;37:1036-42.*

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